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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Thomas M. DiMauro, Mohamed Attawia, Hassan Serhan, Melissa Grace, Michael Slivka, Thomas G. Ferro, Vivek N. Shenoy, Alonzo D. Cook and Scott Bruder

Application No.: 10/723,250

Group Art Unit: 1617

Filed: November 26, 2003

Examiner: Leonard M. Williams

Confirmation No.: 6059

Title: LOCAL INTRAOSSEOUS ADMINISTRATION OF BONE FORMING AGENTS
AND ANTI-RESORPTIVE AGENTS, AND DEVICES THEREFOR

CERTIFICATE OF MAILING OR TRANSMISSION

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9-18-06

Date

Amy T. Comeau

Signature

Amy T. Comeau

Typed or printed name of person signing certificate

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application file.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references [B20-B22, C117-C130] are enclosed.
 - ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
 - ☒ The listed references [B20-B21, C117-C119, C123-C124] were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☐ The "concise explanation" requirement (non-English references) for references [] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

- ☐ Applicant requests that the following non-published pending applications be considered:
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

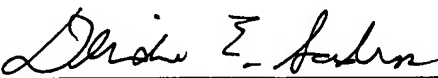
It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 
Deirdre E. Sanders
Registration No.: 42,122
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated:

September 18, 2006

FD-1449 REPRODUCED

**INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATION**

September 15, 2006

(Use several sheets if necessary)

 ATTORNEY DOCKET NO.
3518.1024-000

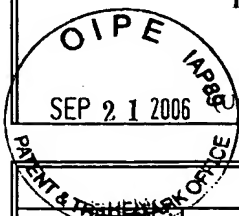
 APPLICATION NO.
10/723,250

 FIRST NAMED INVENTOR
Thomas M. DiMauro

 FILING DATE
November 26, 2003

 EXAMINER
Leonard M. Williams

 CONFIRMATION NO.
6059

 GROUP
1617

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A45	6,756,215 B1	06-29-2004	Wolfrain <i>et al.</i>
	A46	5,194,596	03-16-1993	Tischer <i>et al.</i>
	A47	2002/0082697 A1	06-27-2002	Damien
	A48	2004/0022864 A1	02-05-2004	Freyman <i>et al.</i>
	A49	2004/0126372 A1	07-01-2004	Banerjee <i>et al.</i>
	A50	6,340,369 B1	01-22-2002	Ferree

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	B20	WO 2005/110276 A1	11-24-2005	Massachusetts General Hospital		
	B21	WO 2005/000283 A2	01-06-2005	DePuy Spine, Inc.		
	B22	WO 2006/031376 A2	03-23-2006	DePuy Spine, Inc.		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	C117	Hawks, D., "Alternative Medicine: Musculoskeletal System," <i>Clin. Tech. Small Anim. Pract.</i> , 17(1):41-49 (2002).
	C118	Khot, A. <i>et al.</i> , "The Use of Intradiscal Steroid Therapy for Lumbar Spinal Discogenic Pain - A Randomized Controlled Trial," <i>Spine</i> , 29(8):833-837 (2004).
	C119	Földes, I. <i>et al.</i> , "Trace Elements in Tissues of Normal and Vitamin D ₂ -Treated Rats," <i>ACTA Biol. Acad. Sci. Hung.</i> , 26(3-4):141-150 (1975).
	C120	Benjamin, L.E. <i>et al.</i> , "A Plasticity Window for Blood Vessel Remodelling is Defined by Pericyte Coverage of the Preformed Endothelial Network and is Regulated by PDGF-B and VEGF," <i>Development</i> , 125:1591-1598 (1998).
	C121	Vukicevic, S. <i>et al.</i> , "Induction of Nephrogenic Mesenchyme by Osteogenic Protein 1 (Bone Morphogenetic Protein 7)," <i>Proc. Natl. Acad. Sci.</i> , 93:9021-9026 (1996).

EXAMINER

DATE CONSIDERED

P7-1449 REPRODUCED INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION September 15, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3518.1024-000		APPLICATION NO. 10/723,250	
	FIRST NAMED INVENTOR Thomas M. DiMauro		FILING DATE November 26, 2003	
	EXAMINER Leonard M. Williams		CONFIRMATION NO. 6059	GROUP 1617

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C122	Moreira, A.L. <i>et al.</i> , "Thalidomide Exerts Its Inhibitory Action on Tumor Necrosis Factor α by Enhancing mRNA Degradation," <i>J. Exp. Med.</i> , 177:1675-1680 (1993).	
C123	CN 1 647 808 A (Zhou C) 2005-08-03 (abstract) World Patents Index [online]. London, GB: Derwent Publications, Ltd., Week 200621, Class B04, Accession No. 2006-194507.	
C124	CN 1 569 039 A (Niu X) 2005-01-26 (abstract) World Patents Index [online]. London, GB: Derwent Publications, Ltd., Week 200577, Class B04, Accession No. 2005-749289.	
C125	Shiel, W.C., Ankylosing Spondylitis, MedicineNet.com [online], September 2005 [retrieved on 2006-06-20]. Retrieved from the Internet <URL: http://www.medicinenet.com/script/main/art.asp?articlekey=274&pf=3&page=2 >.	
C126	Sampaio, E.P. <i>et al.</i> , "Thalidomide Selectively Inhibits Tumor Necrosis Factor α Production by Stimulated Human Monocytes," <i>J. Exp. Med.</i> , 173:699-703 (1991).	
C127	Muller, G.W. <i>et al.</i> , "Amino-Substituted Thalidomide Analogs: Potent Inhibitors of TNF- α Production," <i>Bioorg. Med. Chem. Lett.</i> , 9:1625-1630 (1999).	
C128	Teo, S.K., "Properties of Thalidomide and its Analogues: Implications for Anticancer Therapy," <i>AAPS Journal</i> 7(1):E14-E19 (2005).	
C124	Crevensten, G. <i>et al.</i> , "Intervertebral Disc Cell Therapy for Regeneration: Mesenchymal Stem Cell Implantation in Rat Intervertebral Discs," <i>Ann. Biomed. Eng.</i> , 32(3):430-434 (2004).	
C130	Tracey, K.J. and Cerami, A., "Tumor Necrosis Factor in Metabolism of Disease: Hormonal Actions Versus Local Tissue Effects," <i>Nouv. Rev. Fr. Hematol.</i> , 34 Suppl:S37-42 (1992) (abstract).	

EXAMINER	DATE CONSIDERED
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